MAR 1 4 2014

Abbreviated 510k
STERISPINE® LC
Lumbar Cage

SafeOrthopaedics

510(k) SUMMARY

Submitted by	Safe Orthopaedics Parc des Bellevues Allée R. Luxembourg - Le Californie 95610 Eragny sur Oise – FRANCE
Contacts	QARA Director : Pierre DUMOUCHEL p.dumouchel@safeorthopaedics.com +33 (0) 1 34 21 50 00 Regulatory contact Isabelle Drubaix idee-consulting@nordnet.fr +33 (0)3 21 05 64 23
Date Prepared	December 9th 2013
Common Name	Intervertebral body fusion device
Trade Name	SteriSpine™LC Lumbar Cage
Classification Name	Intervertebral Fusion Device With Bone Graft, Lumbar
Class	II
Product Code	MAX
CFR section	888.3080
Device panel	ORTHOPEDIC
Legally marketed predicate devices	STERISPINE™ LC manufactured by Safe Orthopaedics and cleared under K122021, Crescent manufactured by Medtronic and cleared under K094025 and Lumbar I/F cage manufactured by Depuy and cleared under P960025
Indications for use	The SteriSpine™LC device is indicated for intervertebral body fusion procedures at one or two contiguous levels from L2 to S1 in skeletally mature patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage. This device is to be used with autogenous bone graft to facilitate fusion and is intended for use with SteriSpine™ PS, a supplemental fixation system cleared by the FDA for use in the lumbar spine.
Description of the device	The SteriSpine™LC cages are intervertebral body fusion devices with a central cavity that is filled with bone graft (autograft) to facilitate fusion. The SteriSpine™LC is available either in straight rectangular shape for transforaminal (TLIF) or posterior (PLIF) approach and in curved shape for transforaminal (TLIF) approach. The SteriSpine™LC is made of (Zeniva ZA-500) conforming to ASTM F2026 with Tantalum markers conforming ASTM F560 to visualize the position of the implant in the disc space. The SteriSpine™LC cages are available in several sizes to adapt to anatomical variations.

Technological Characteristics	The SteriSpine™LC straight cages are available in 8 heights (from 7 to 14 mm) and six lengths (from 22 to 32 mm) with a 4° lordosis. The SteriSpine™LC curved cages are available in 8 heights (from 7 to 14 mm) and three lengths (from 28 to 32 mm) with a 4° lordosis. The SteriSpine™LC range of products is supplied sterile with a sterile single-use set of surgical instruments.
Discussion of Testing	The following non-clinical tests were conducted on SteriSpine™LC : Static axial compression, Dynamic axial compression, Static compression shear testing and Dynamic compression shear testing according to ASTM F2077, subsidence testing according to ASTM F2267 and and expulsion testing according to in-house protocol. Results demonstrate that SteriSpine™LC performs as safely and effectively as previsoulsy cleared devices.
Conclusion	The SteriSpine™LC devices enclosed within the present submission are substantially equivalent to previously cleared SteriSpine™LC devices in terms of intended use, material, design, mechanical properties and function. The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Non clinical performance testing demonstrates that SteriSpine™LC is as safe, as effective, and performs as safely and effectively as its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 14, 2014

Safe Orthopaedics
Mr. Pierre Dumouchel
QARA Director
Parc des Bellevues
Allée R. Luxembourg – Le Californie
95610 Eragny sur Oise – FRANCE

Re: K133893
Trade/Device Name: SteriSpine™ LC Lumbar Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: December 17, 2013
Received: December 20, 2013

Dear Mr. Dumouchel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K133893

Device Name: SteriSpine™LC

Indications for Use:

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This device is to be used with autogenous bone graft to facilitate fusion and is intended for use with SteriSpine™ PS, a supplemental fixation system cleared by the FDA for use in the lumbar spine.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Colin O'Neill

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K133893